GAU 1614

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May 3, 2002 — Mark A. Wilson

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Attorney Docket No. 6200-0013
PATENT

#8
5-25-02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In Re Application of:
Feng-Jing CHEN et al.

Serial No.: 09/716,029 — Group Art Unit: 1614

Filing Date: November 17, 2000 — Examiner: Brian Kwon

Title: PHARMACEUTICAL COMPOSITIONS AND DOSAGE FORMS FOR ADMINISTRATION OF HYDROPHOBIC DRUGS

COPY OF PAPERS ORIGINALLY FILED

RESPONSE TO REQUIREMENT FOR RESTRICTION

Commissioner for Patents
Washington, D.C. 20231

Sir:

This is in response to a communication mailed from the PTO on April 3, 2002, requiring restriction. As this response is being mailed within the one-month shortened statutory period, no extension of time is necessary.

THE STATED REQUIREMENT FOR RESTRICTION:

In the Office Action under reply, restriction has been required to one of the following subject matter groupings:

Group I - claims 1, 3-12, 37, 38, 40-46, 50 and 52-90, drawn to a fenofibrate containing composition; and

Group II - claims 51 and 91-94, drawn to a method of treating a lipid disorder with the aforementioned composition.

Claim 50, directed to a composition comprising a hydrophobic drug (not necessarily fenofibrate), appears correctly included in Group I since this claim encompasses a composition.

Further, if the claims of Group I are elected, the Examiner has further required restriction of the claims of Group I, as follows:

Group Ia - claims 1, 3, 4, 37, 38, 40, 41, 44-46, 52 and 53, drawn to a composition comprising a combination of fenofibrate and a vitamin E substance;

Group Ib - claims 5-12, 42, 43, 54-65 and 75-79, drawn to a composition comprising a combination of fenofibrate and a solubilizer selected from the group consisting of a trialkyl citrate, a lactone, a nitrogen-containing solvent and combinations thereof; and

Group Ic - claims 66-74 and 80-90, drawn to a composition comprising fenofibrate and a vitamin E substance in combination with a solubilizer selected from the group consisting of a trialkyl citrate, a lactone, a nitrogen-containing solvent and combinations thereof.

Presumably, Group Ia also includes claim 50 as this claim encompasses a composition comprising a vitamin E substance.

ELECTION AND REASONS FOR TRAVERSE:

In response, applicants elect the claims of Group Ia, **with traverse** with respect to *both* the restriction between the claims of Groups I and II and the further restriction between the claims of Groups Ia, Ib and Ic.

In making the initial restriction between the claims of Group I and II, the Examiner emphasizes the distinctiveness between claims directed to a product (e.g., Group I) and claims directed to a process of use (e.g., Group II). In the present case, however, the restriction between the composition claims and the corresponding method of treatment claims is clearly improper, as explained below.

In a previous Requirement for Restriction dated May 16, 2001, the Examiner stated that claim 51, directed to a method of treatment based on administering a claimed composition, would be included in any composition election since the method of treatment claim contained "common limitations" with the composition claims. Relying on the Examiner's remarks that restriction would not be required between composition claims and method of treatment claims having common limitations, applicants elected (without traverse) claims 1-12 and 37-51 in their response with the understanding that such method of treatment claims would be examined along with the elected composition claims. See page 3 of the Preliminary Amendment and Response to the Requirement for Restriction filed June 18, 2001. Thereafter, the Examiner searched and examined *both the elected composition claims as well as the corresponding treatment method claims* as evidenced by the Office Action dated July 24, 2001. In now requiring the present restriction between the composition claims of Group I and the method of treatment claims of

Group II, the Examiner has not only completely reversed himself, but has prejudiced applicants as well.

The method claims presently before the Examiner still have common limitations with the composition claims. Therefore, the present and unexpected restriction between the composition and corresponding method of treatment claims unnecessarily delays, and, in fact, represents a regression of, prosecution of the current application. A requirement for restriction between composition and method claims could have been made nearly a year ago in the May 16, 2001 Requirement for Restriction. Had the Examiner issued such a requirement for restriction at that time, applicants would have responded differently and the current procedural posture would inevitably be very different. Now that applicants have followed the Examiner down one path of prosecuting the application, it is prejudicial to suddenly backtrack prosecution by issuing a restriction that was deemed to be unnecessary by the Examiner one year ago, and which the Examiner explicitly stated that he would not make. Certainly the Examiner, as well as the Applicants, is interested in the expeditious prosecution of the current application; forcing applicants to now elect between composition and method claims not only hinders efficient prosecution of the application, but also prejudices applicants.

Furthermore, the restriction is unnecessary in the present case. Specifically, *a search encompassing both the composition and method claims has already been carried out.* On this point, applicants respectfully direct the Examiner's attention to Section 803 of the M.P.E.P., where it is stated that "[i]f a search and examination . . . can be made without serious burden, the examiner must examine it on the merits . . . ." There is no serious burden when the Examiner *has already carried out the required search.* Consequently, applicants respectfully request reconsideration and removal of the restriction between the claims of Group I and Group II.

With respect to the further restriction between the claims of Groups Ia, Ib and Ic, applicants also believe that such a restriction is improper. Again, as noted above, a search has already been carried out. No additional search appears necessary. Specifically, the subject matter of claims 1-12 and 37-51 has already been searched and examined as a result of applicants' prior election. That is, compositions (and methods of using these claimed compositions) comprising a hydrophobic active agent, e.g., fenofibrate, a vitamin E substance, a trialkyl citrate, a lactone, a nitrogen-containing solvent or combination thereof *have already been searched by the Examiner.* This completed search covers all of the subject matter

encompassed by the currently pending claims. Consequently, no additional search appears warranted.

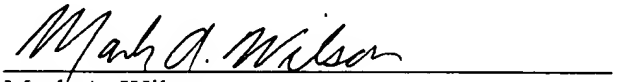
Furthermore, a search of the subject matter of Group Ia, directed to a composition "comprising" a combination of fenofibrate and a vitamin E substance, would necessarily include a search of Group Ic, directed to a composition comprising a combination of fenofibrate, a vitamin E substance and another solubilizer. Therefore, no additional search should be required to examine the claims of Group Ic upon completion of a search of the broader subject matter encompassed by the claims of Group Ia. Similarly, no additional search should be required to examine the claims of Group Ic should Group Ib be elected. Thus, as between the subject matter of Groups Ia and Ib, and of Groups Ia and Ic, no restriction is necessary. For all the foregoing reasons, applicants respectfully request that the Examiner reconsider and withdraw the restriction between Groups Ia, Ib and Ic.

CONCLUSION

Accordingly, applicants respectfully request reconsideration and removal of the restriction between the claims of Group I and Group II. Furthermore applicants respectfully request that the Examiner reconsider and withdraw the restriction between Groups Ia, Ib and Ic.

The Examiner is welcome to contact the undersigned at 650-330-0900 with any questions he may have concerning this communication or the subject application.

Respectfully submitted,

By: 

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